MAR - 6 2014

510(k) Summary K133966

Halifax Biomedical Inc.
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Contact: Chad Munro, CEO President
Date Prepared: February 20, 2014

1. Identification of the Device:

Proprietary-Trade Name:	Model-based RSA Software
Product Code	LLZ
Device:	System, Image Processing, Radiological
Regulation Description:	Picture archiving and communications system.
Regulation Medical Specialty	Radiology
Regulation Number	892.2050
Device Class	2

2. Equivalent legally marketed devices:. The Model-based RSA Software employs the software cleared in K042383, the RSA-CMS.

3. Indications for Use (intended use): Orthopaedic specialists and/or Halifax Biomedical Inc image processing labs use the Model - based RSA Software as standalone analytical software package for the evaluation of orthopaedic implant fixation, bone segment motion. Model - based RSA software measures the in - vivo 3D position and/or relative motion of metal implants, marker beads, and/or bone segments. When interpreted by trained physicians these measurements may be useful to derive conclusions for patient treatment. NOT FOR MAMMOGRAPHY.

4. Description of the Device: This is a Windows based software only product. It represents an advancement and extension of the same software cleared in K042383. Model-based RSA (Roentgen Stereophotogrammetric Analysis) is a stand-alone analytical software package for RSA digital image post-processing that runs on standard workstations running a Microsoft Windows operating system. This software is used to analyze roentgen images. It accepts digital images in the specific formats from all the major roentgen manufacturers (DICOM - CR and DX modality) as well as scanned roentgen films in bitmap (BMP) format. Generally, a pair of stereo roentgen images is taken of a patient's joint pre-operatively or postoperatively at one or more time points. Model-based RSA software is then used to measure the three dimensional (3D) relative position and/or relative motion of 3D models in the RSA images. Models may generally represent orthopaedic implants, a group of implanted markers (small tantalum beads), or bones. The 3D relative position and/or relative motion measures may provide information regarding loosening of implants, wear of implants, and excessive or reduced motion between bones such as in spine instability and spine fusion

5. Safety and Effectiveness, comparison to predicate device. The results of software validation, clinical evaluation, and risk analysis indicates that the new device is as safe and effective as the predicate device.

6. Substantial Equivalence Chart, Model-based RSA Software: Please see the chart below.

K133966
Page 2 of 2

Characteristic	K042383, the RSA-CMS.	Model-based RSA Software
Intended Use:	RSA-CMS has been developed for the objective and reproducible analysis on digital roentgen images (DICOM CR or DX) or digitised images in a PACS environment. Orthopedic specialist and core labs use the RSA-CMS standalone analytical software package In image post-processing for the evaluation of new implant designs, coatings and new cementation techniques in clinical trials. When interpreted by trained physicians these parameters may be useful to derive conclusions from these clinical trials.	Orthopaedic specialists and/or Halifax Biomedical Inc. image processing labs use the Model-based RSA Software as standalone analytical software package for the evaluation of orthopaedic implant fixation , bone segment motion. Model-based RSA software measures the in-vivo 3D position and/or relative motion of metal implants, marker beads, and/or bone segments. When interpreted by trained physicians these measurements may be useful to derive conclusions for patient treatment. NOT FOR MAMMOGRAPHY.
Target Users	Trained physicians	SAME
Specialty	Orthopaedic	SAME
Image Types	DICOM, BMP, TIFF	Same
PC Workstation	Yes	Yes
Receive digital images from various sources	Yes	Yes
Transmit data to remote viewing PACS stations over a medical imaging network	Yes	No
Digital image post processing	Yes	Yes
Scaling of image facility	Yes	Yes
Measurement capabilities	Yes	Yes
Preoperative Planning	No	Yes
Assessment of 2D migration of prostheses	Yes	Yes
Assessment of 3D migration of prostheses	Yes	Yes

7. Description of non-clinical (bench) testing: Software documentation was executed according to the recommendations of the FDA Guidance Document: Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices Document issued on: May 11, 2005. This included validation and risk analysis. Validation of Model-based RSA software is done by comparing the calculated migrations with accurately applied translations and rotations using a micromanipulator in phantom experiments.

8. Description of clinical testing: Clinical experiments studied the accuracy and precision of migration calculations using Model-based RSA. Five studies in all showed that migration calculations by the Model-based RSA software are not biased and have high accuracy and precision.

9. Conclusion: After analyzing software validation, bench tests, clinical data, and risk analysis, it is the conclusion of Halifax Biomedical that the Model-Based RSA Software is as safe and effective as the predicate devices, has no significant technological differences, and has no new indications for use, (In fact USING the predicate devices) thus rendering it substantially equivalent to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

March 6, 2014

Halifax Biomedical, Inc.
% Mr. Daniel Kamm
Principal Engineer
Kamm & Associates
8870 Ravello Court
NAPLES FL 34114

Re: K133966
Trade/Device Name: Model-Based RSA Software
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: LLZ
Dated: December 20, 2013
Received: December 24, 2013

Dear Mr. Kamm:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for

Janine M. Morris
Director, Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known):K133966

Device Name: Model-Based RSA Software

Indications For Use:
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Prescription Use X AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH. Office of *In Vitro* Diagnostics and Radiological Health (OIR)

(Division Sign-Off)
Division of Radiological Health
Office of *In Vitro* Diagnostics and Radiological Health

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